

AMENDMENTS TO THE CLAIMS

This listing of claims will replace all prior versions, and listings, of claims in the application:

Listing of Claims:

1-40 (Cancelled).

41(New). A parenteral composition comprising:

(i) a first mixture of about 1 to about 25 mg/mL of CCI-779, about 15 to about 60% w/v of dehydrated ethanol, about 0.01 to about 0.1% w/v of d,l- α -tocopherol, about 0.001 to about 0.005% w/v of citric acid, and about 15 to about 60% w/v of propylene glycol, and

(ii) a second mixture of about 15 to about 60% w/v of polysorbate 80, 15 to 60% w/v of polyethylene glycol 400, and about 15 to about 60% w/v of dehydrated ethanol.

42(New). The parenteral composition according to claim 41, wherein (i) and (ii) are present in a ratio of about 1:1.5 to 1:2.

43(New). The parenteral composition according to claim 41, comprising about 10 mg/mL of CCI-779.

44(New). The parenteral composition according to claim 41, comprising about 0.0025 to about 0.005% w/v of citric acid.

45(New). The parenteral composition according to claim 41, comprising:

- (i) a first mixture of about 25 mg/mL CCI-779, about 40% w/v of dehydrated ethanol, about 0.075% w/v of d,l- α -tocopherol, about 0.0025% w/v of citric acid, and 35% w/v propylene glycol, and
- (ii) a second mixture of about 20% w/v of dehydrated ethanol, about 40% w/v of polysorbate 80, and about 40% w/v of polyethylene glycol 400.

46(New). The parenteral composition according to claim 45, wherein (i) and (ii) are present in a ratio of about 1:1.5.

47(New). The parenteral composition according to claim 41, comprising:

- (i) a first mixture of about 1 to about 25 mg/mL of CCI-779, about 40% w/v of dehydrated ethanol, about 0.075% w/v of d,l- α -tocopherol, about 0.0025% w/v of citric acid, and q.s. of propylene glycol, and
- (ii) a second mixture of about 40% w/v of polysorbate 80, about 20% w/v of polyethylene glycol 400, and about 40% w/v of dehydrated ethanol.

48(New). A parenteral composition comprising:

- (i) a first mixture of about 1 to about 25 mg/mL of CCI-779, about 15 to about 60% w/v of dehydrated ethanol, about 0.01 to about 0.1% w/v of d,l- α -tocopherol, and about 15 to about 60% w/v of propylene glycol, and
- (ii) a second mixture of about 15 to about 60% w/v of polysorbate 80, 15 to 60% w/v of polyethylene glycol 400, and about 15 to about 60% w/v of dehydrated ethanol.

49(New). A parenteral composition consisting of:

- (i) a concentrate of about 1 to about 25 mg/mL of CCI-779, about 0.01 to 0.1% w/v of d,l- α -tocopherol, about 0.001 to about 0.005% w/v of citric acid, and about 15 to about 60% w/v of dehydrated ethanol and propylene glycol, and

(ii) a diluent of about 15 to about 60% w/v of polysorbate 80, 15 to 60% w/v of polyethylene glycol 400, and about 15 to about 60% w/v of dehydrated ethanol.

50(New). The parenteral composition according to claim 49, wherein (i) and (ii) are present in a ratio of about 1:1.5 to 1:2 of concentrate to diluent.

51(New). The parenteral composition according to claim 49, consisting of about 10 mg/mL of CCI-779.

52(New). A parenteral composition consisting of:

(i) a concentrate of about 1 to about 25 mg/mL of CCI-779, about 0.01 to 0.1% w/v of d,l- α -tocopherol, and about 15 to about 60% w/v of dehydrated ethanol and propylene glycol, and

(ii) a diluent of about 15 to about 60% w/v of polysorbate 80, 15 to 60% w/v of polyethylene glycol 400, and about 15 to about 60% w/v of dehydrated ethanol.

53(New). A parenteral composition comprising:

- (i) about 1 to about 25 mg/mL of CCI-779,
- (ii) about 0.01 to 0.1% w/v of d,l- α -tocopherol,
- (iii) about 0.001 to about 0.005% w/v of citric acid,
- (iv) about 15 to about 60% w/v of a combination of dehydrated ethanol and propylene glycol, and
- (v) about 15 to about 60% w/v of a combination of polysorbate 80 and polyethylene glycol 400.

54(New). The parenteral composition according to claim 53, wherein the ratio of polysorbate 80 to polyethylene glycol 400 is about 1:1.

55(New). The parenteral composition according to claim 53, wherein the ratio of dehydrated ethanol to propylene glycol in (iv) is about 1.4:1.

56(New). The parenteral composition according to claim 53, wherein the ratio of component (iv) to (i) is about 50:1.

57(New). The parenteral composition according to claim 53, wherein the ratio of component (v) to (i) is about 50:1.

58(New). A parenteral composition comprising:

- (i) about 1 to about 25 mg/mL of CCI-779,
- (ii) about 0.01 to 0.1% w/v of d,l- α -tocopherol,
- (iii) about 0.001 to about 0.005% w/v of citric acid,
- (iv) about 15 to about 60% w/v of a combination of dehydrated ethanol and propylene glycol, wherein the ratio of dehydrated ethanol to propylene glycol is about 1.4:1, and
- (v) about 15 to about 60% w/v of a combination of polysorbate 80 and polyethylene glycol 400, wherein the ratio of polysorbate 80 to polyethylene glycol 400 is about 1:1;

wherein:

the ratio of mixture (iv) to (i) is about 50:1; and

the ratio of mixture (v) to (i) is about 50:1.

59(New). A parenteral composition comprising:

- (i) about 1 to about 25 mg/mL of CCI-779,
- (ii) about 0.01 to 0.1% w/v of d,l- α -tocopherol,
- (iii) about 15 to about 60% w/v of a combination of dehydrated ethanol and propylene glycol, wherein the ratio of dehydrated ethanol to propylene glycol is about 1.4:1, and

(iv) about 15 to about 60% w/v of a combination of polysorbate 80 and polyethylene glycol 400, wherein the ratio of polysorbate 80 to polyethylene glycol 400 is about 1:1;

wherein:

the ratio of mixture (iii) to (i) is about 50:1; and

the ratio of mixture (iv) to (i) is about 50:1.

60(New). A parenteral composition comprising:

(i) about 2.5% w/v of CCI-779, about 0.0075 w/v of d,l- α -tocopherol, about 0.0025% w/v of citric acid, about 40% w/v of dehydrated ethanol, and about 50% w/v of propylene glycol, and

(ii) about 40% w/v of polysorbate 80, about 20% w/v of dehydrated ethanol, and about 43% w/v of polyethylene glycol 400.

61(New). The parenteral composition according to claim 60, wherein (i) and (ii) are present in a ratio of about 1:1.5 to 1:2.

62(New). A parenteral composition comprising:

(i) about 1% w/v of CCI-779,

(ii) about 0.03% w/v of d,l- α -tocopherol,

(iii) about 0.001% w/v of citric acid,

(iv) about 28% w/v of dehydrated ethanol,

(v) about 20% w/v propylene glycol,

(vi) about 24% w/v of polysorbate 80 and

(vii) about 26% w/v of polyethylene glycol 400.

63(New). A process for preparing a parenteral composition of claim 41, said process comprising combining mixtures (i) and (ii).

64(New). The process according to claim 63, further comprising combining mixtures (i) and (ii) with water.